Anti-SARS-CoV-2 QuantiVac ELISA (IgG)

- **Specific ELISA for the quantitative detection of anti-SARS-CoV-2 IgG by means of a 6-point calibration curve**
- **Enables exact determination of the course of concentration of IgG antibodies against the S1 antigen, including the immunologically relevant receptor binding domain (RBD), over a broad linear range**
- **Excellent correlation with the Working Standard NIBSC Anti-SARS-CoV-2 Antibody Diagnostic Calibrant (NIBSC code 20/162) and the Neutralization Antibody Detection Kit from GenScript USA, Inc.**
- **Validated for serum, plasma and dried capillary blood as sample material**

Technical data

Antigen	S1 domain of the spike protein of SARS-CoV-2, recombinantly produced in human cells
Calibration	Quantitative, in relative units per millilitre (RU/ml) Calibrator 1: 120 RU/ml Calibrator 2: 80 RU/ml Calibrator 3: 40 RU/ml Calibrator 4: 20 RU/ml Calibrator 5: 10 RU/ml Calibrator 6: 1 RU/ml Recommended upper threshold of the reference range for non-infected individuals (cut-off): 10 RU/ml
Sample dilution	Serum or plasma, 1 : 101 in sample buffer, or 4.76 mm membrane piece containing dried capillary blood (punched out from Blood Collection Card) in 250 µl sample buffer
Reagents	Ready for use, with the exception of the wash buffer (10x); colour-coded solutions, in most cases exchangeable with those in other EUROIMMUN ELISA kits
Test procedure	60 min (37 °C) / 30 min (37 °C) / 30 min (RT) (sample/conjugate/substrate incubations), fully automatable
Measurement	450 nm, reference wavelength between 620 nm and 650 nm
Test kit format	96 break-off wells; kit includes all necessary reagents
Stability	12 months
Order number	**EI 2606-9601-10 G**

Clinical significance

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2, previously called 2019-nCoV) belongs to the family of coronaviruses and, like SARS-CoV, is classified in the genus *Betacoronavirus*. At the end of 2019, SARS-CoV-19 was identified as the causative pathogen of clustered cases of pneumonia of unclear origin. The virus caused an infection wave which quickly spread worldwide and was declared a pandemic by the WHO at the beginning of 2020. The disease caused by SARS-CoV-2 is called COVID-19.

SARS-CoV-2 is predominantly transmitted by respiratory uptake of virus-containing droplets and aerosols produced during speaking, breathing, coughing or sneezing. The incubation time of SARS-CoV-2 is three to seven, maximally 14 days. The infection may manifest asymptomatically or with symptoms of a febrile illness with irregular lung infiltrates. Some patients, especially elderly or chronically ill patients, develop acute respiratory distress syndrome (ARDS).

Suitable methods for the diagnosis of SARS-CoV-2 infections are the detection of viral RNA by reverse transcriptase polymerase chain reaction (RT-PCR) or of virus protein by means of ELISA primarily in sample material from the upper (nasopharyngeal or oropharyngeal swab) or lower respiratory tract (bronchoalveolar lavage fluid, tracheal secretion, sputum, etc.). The determination of antibodies enables confirmation of SARS-CoV-2 infection in patients with typical symptoms and in suspected cases. It also contributes to monitoring and outbreak control. For significant serological results, two patient samples should be investigated, one from the acute phase (week 1 of the illness) and one from the convalescent phase (three to four weeks later). Cross-reactions of antibodies within the genus *Betacoronavirus* have been described.

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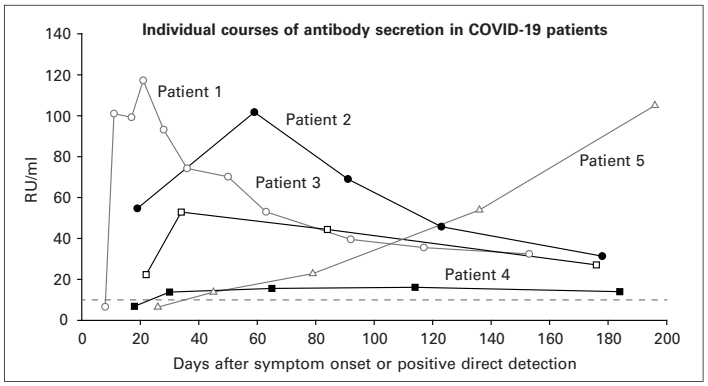
Diagnostic sensitivity*

The sensitivity was determined by investigating 202 samples from 194 patients (origin: Europe, USA) using the Anti-SARS-CoV-2 QuantiVac ELISA (IgG). These patients had been confirmed to be infected with SARS-CoV-2 by RT-PCR based on a sample taken at the early phase of infection. The serological analysis was performed with samples taken during the further course of the infection. In samples collected up to day 10 (time point after the onset of symptoms or positive direct detection), the Anti-SARS-CoV-2 QuantiVac ELISA (IgG) showed a sensitivity of 56.7 %. In samples collected after day 10, the sensitivity of the Anti-SARS-CoV-2 QuantiVac ELISA (IgG) amounted to 90.3 %. Borderline results (n = 7) were excluded. From the 46 patients with SARS-CoV-2 infection confirmed by RT-PCR based on one sample from the early infection phase, several consecutive samples were available. In 93.2 % of the patients the antibody test was positive over the course from day 21 post symptom onset or positive direct detection (borderline results (n = 2) excluded).

The time course of antibody secretion and the antibody activity at specific time points can vary significantly. In most patients, antibodies are detectable after day 10 post symptom onset or positive direct detection. In individual cases, a strongly delayed synthesis of IgG (> 4 weeks after onset of symptoms or positive direct detection) has been reported. The graphic shows individual immune responses in COVID-19 patients which were determined using the EUROIMMUN Anti-SARS-CoV-2 QuantiVac ELISA (IgG).

*The sensitivity depends on the prevalence of specific IgG antibodies in persons with SARS-CoV-2 infections



Specificity

The specificity of the Anti-SARS-CoV-2 QuantiVac ELISA (IgG) was determined by analysing 210 patient samples that were positive for antibodies against other human pathogenic coronaviruses, other pathogens or for rheumatoid factors, as well as samples collected from 230 asymptomatic and symptomatic donors during the Zika virus outbreak in Colombia. Additionally, 1018 samples from blood donors, children and pregnant women obtained prior to the occurrence of SARS-CoV-2 (before January 2020) were analysed. The specificity of the Anti-SARS-CoV-2 QuantiVac ELISA (IgG) amounted to 99.8 %.

Panel	EUROIMMUN Anti-SARS-CoV-2 QuantiVac ELISA (IgG)	
	n	Specificity
Blood donors	849	99.9 %
Pregnant women	99	99.0 %
Children	70	100 %
Elderly patients	97	100 %
Asymptomatic donors during the Zika virus outbreak 2015/16 (Colombia)	150	100 %
Symptomatic donors during the Zika virus outbreak 2016/17 (Colombia)	80	98.7 %
Infections with other human pathogenic coronaviruses	11	100 %
Influenza (freshly vaccinated, incl. courses)	40	100 %
Acute EBV infection & heterophilic antibodies	22	100 %
Rheumatoid factors	40	100 %
Total	**1458**	**99.8 %**

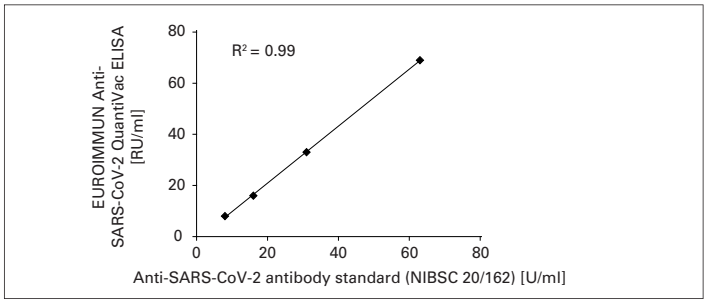
Borderline results (n = 5) were not included.

Correlation

46 samples from a mixed panel (14 samples from healthy blood donors (collected before January 2020), 30 samples from patients with SARS-CoV-2 infections collected > 10 days after positive direct detection or symptom onset, and 2 commercial anti-SARS-CoV-2 IgG-positive samples) were investigated using the Anti-SARS-CoV-2 QuantiVac ELISA (IgG) from EUROIMMUN and the cPass SARS-CoV-2 Neutralization Antibody Detection Kit from GenScript. The agreement of qualitative results obtained with the two tests was 97.8 %.

n=46		GenScript cPass SARS-CoV-2 Neutralization Antibody Detection Kit	
		positive	negative
EUROIMMUN Anti-SARS-CoV-2 QuantiVac ELISA (IgG)	positive	30	0
	negative	1	15

Serial dilutions of the Working Standard NIBSC Anti-SARS-CoV-2 Antibody Diagnostic Calibrant (NIBSC code: 20/162) were investigated using the Anti-SARS-CoV-2 QuantiVac ELISA (IgG). The linear regression analysis yielded a correlation coefficient of $R^2 = 0.99$.



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